

January 2005



## THE REGULATOR for the well informed lab

# PROFICIENCY TESTING FOR CYTOLOGY IS UPON US!

The CLIA program has notified all State Agencies that Cytology Proficiency Testing (PT) is now available.....and you know you have to enroll and participate. Two agencies have been approved by the Central Office:

State of Maryland Cytology Proficiency Testing Program  
Midwest Institute for Medical Education (MIME).

There is one hitch. If you don't examine specimens from Maryland patients, you can't enroll in their program at this time.??

The CLIA regulations at 42 CFR 493.855 requires successful participation and each laboratory is responsible for ensuring that each individual engaged in the examination of gynecologic preparations is enrolled in a proficiency testing program. Your choices are listed above. All individuals mean all individuals, including (gasp) pathologists.

All labs doing exfoliative cytology should enroll by June 2005 and be tested in 2005 as well. CLIA strongly encourages prompt enrollment. While compliance in 2005 is expected, labs have until April 2, 2006 to ensure that all individuals reading PAP smears have been tested at least once. You are given until December 2006 to ensure that all affected individuals has achieved a passing score. There are the usual enforcement actions if compliance has not been achieved by the December deadline.

Since you are essentially down to the MIME agency, the State advises you not to linger on the path because it is not known whether MIME can handle the entire country sans Maryland. First come is first served. You must enroll in the approved PT program by June 2005.

Georgia is required to send an alert notice to you and a copy to CMS. If the laboratory is not to be surveyed in 2005, it must send an attestation document, signed by the lab director, that confirms all affected individuals are enrolled in a PT program.

All individuals must have a passing score by December 31, 20006.

QUESTIONS?????

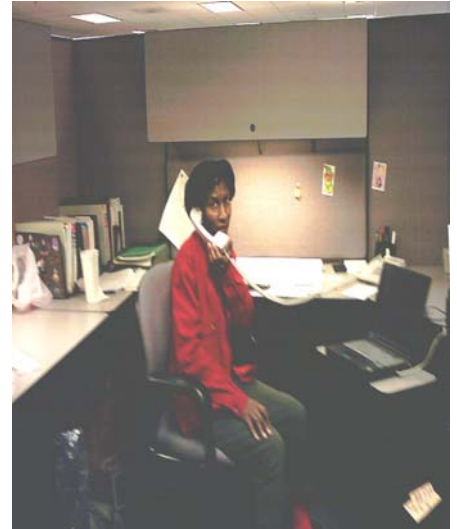
Jeannie Arnold

404-657-5447/5448

## Proficiency Testing Hints

The Office sends out two types of problem proficiency testing letters. One is a warning letter that gives you a heads up that a boo-boo has occurred. You are not required to provide a written statement if you receive this letter. What you **should do**, as good laboratory practice, is determine what happened, how it happened and what you are going to put in place to prevent it from happening again. Then place the item on your QA monitoring sheet. The second letter is the real deal and means, not only that you have messed up, but did it twice. This situation **requires a written Plan of Correction to the Statement of Deficiencies** you will receive. You must troubleshoot the area of failure and determine what caused the errors. It will also require reeducation of staff in that area.

Questions? Call Ola Monday at 404-657-5402



## THE LABORATORIANS PRAYER

Grant me, Oh Lord, the genius to follow the plans of this laboratory, though no one has explained them to me. Give me the understanding that I may curb the overanxious supervisor and accept the views of those who do nothing until I have done something, and then tell me what I should have done and how I should have done it.

OH LORD, make me formidable in knowledge, logical in argument and flawless in confrontation. A lawyer, doctor, mathematician, sage, philosopher, sociologist, and an economist; pleasing, cajoling, threatening and belaboring, so that I may make the best of the day, and spare time from no time at all.

Teach me ,oh Lord, to stand firmly on my own two feet, even when I don't have a leg to stand on.

Lord, I am associated with a motley crew. In your infinite wisdom, see my need for all these things and grant them to me.

And when I have them, Lord, MOVE OVER!

# DSU Crew

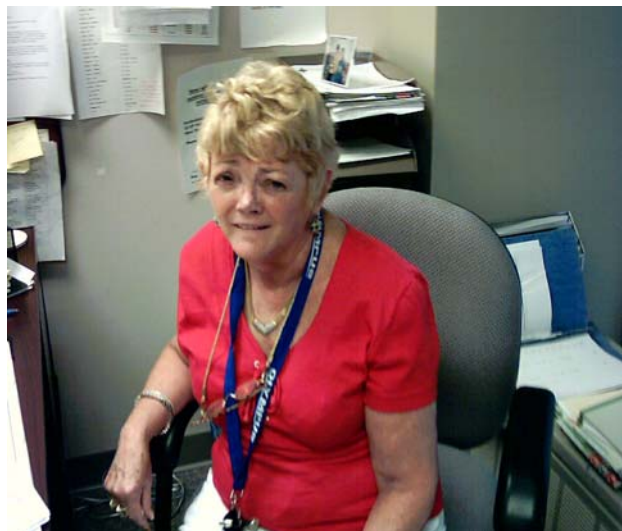
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Please welcome Jeannie Arnold as the new Acting Program Director of the Lab/X-ray Unit. She has been a lab surveyor for 14 years. Jeannie is a BS, MT (ASCP). She received her degree from Berry College in Rome and her Med. Tech training from St. Joseph's Hospital looong ago, when it was in downtown Atlanta. She has mine and Genelle's blessing. My best to you all. Betty Logan



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*Protecting Public Health and Safety Through  
Regulatory Oversight*

## MEET THE DSU STAFF

Betty



Genelle



The time has come to say goodbye. While we are sad, we are also glad that our journey here in the Diagnostic Services Unit is coming to an end. Genelle retires as of January 1, 2005 and I am right behind her on February 1, 2005. I know I speak for both of us when I say that it has been an honor and a pleasure to have served all the clinical laboratories in Georgia. This state has a wonderful and responsive laboratory community and we are proud to have been a part of the group. Clinical Laboratory Science is a noble profession that strives every hour of every day to provide quality health care to the citizens of Georgia. We are proud of you all. Good luck!